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August 14, 2000

Mr. Joseph A. Levitt
Director
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Re: Citizens' Petition for Rules Regarding the Labeling and Manufacture of Foods
Containing Allergenic Substances

Dear Joe:

I am writing in response to the FDA petition regarding food labeling which was filed earlier this year by the Attorneys General of New York, Maryland, Michigan, Wyoming, Ohio, Tennessee, Connecticut, Vermont, and Massachusetts.

As you know, there is no cure for food allergies. Reading ingredient labels and avoiding the food to which one is allergic is the only way to prevent an allergic reaction. FAN applauds reasonable efforts to make label reading clearer, more reliable, and easier for the close to 7 million Americans who have food allergies.

I would like to provide FAN's comments on the Attorney General's recommendations:

- Creating a symbol, a circle with a letter A, to be placed on the front of all packages which contain an allergen. There are several potential problems with using a symbol on the front of a package to identify allergy-causing ingredients; one being that the vast majority of products produced in the U.S. contain one of these ingredients. Food-allergic consumers must have clear, consistent, reliable, and complete information about a product's ingredients on the ingredient declaration. These declarations should have easy-to-understand, simple English terms. For example, milk instead of casein; egg instead of albumin. The circle A designation would not provide allergic consumers with the information that they need to identify the specific type of allergenic food that would be present in the product. Thus, FAN does not believe that the circle A approach will be helpful.

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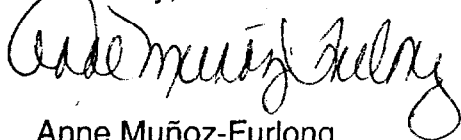
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- Establishing a toll-free hotline. History has shown that ingredients change frequently. What if a hotline's data is not current? What if the hotline information is different from the ingredient information on the product at the store? Once again, FAN believes the emphasis on labeling improvements should be placed on making sure consumers can trust that what is on the ingredient label is what is inside the product. Consumers should not have to go to a toll-free number to get information and then read the label at the store and hope that they both match. They should be able to read the ingredient label and trust what it says.
- Specifying ingredients found at insignificant levels. FAN has long held the position, and has recommended to the food industry and the FDA in the past, that ingredients and the allergenic sources of ingredients should always be declared on the product's label if present in sufficient amounts to elicit allergic reactions. In such situations, terms such as natural flavors should identify common allergens. This approach would be consistent with a 1996 FDA letter to the food industry regarding labeling of processing aids. FAN has long held this position and has recommended to the food industry and the FDA in the past that even trace amounts of an allergen can cause an allergic reaction. Terms such as natural flavors should identify common allergens in situations where levels in the finished product are sufficient to elicit allergic reactions.
- Establishing food industry guidelines to prevent cross contamination. Judicious use of precautionary labeling statements, e.g. "may contain", can be beneficial in certain situations. FAN endorses FDA's past guidance to the food industry in 1996, which advises that precautionary labeling should not be used to allow diminution of good manufacturing practices. FAN agrees that this area needs stronger guidelines. Many of the large food manufacturers have been working on this issue for a number of years, and have made great progress. Other companies have not yet begun to institute this important practice, relying instead on loopholes in labeling standards instead of best manufacturing practices.

Thank you for your time and attention to this important matter. Please let me know if I can provide additional information.

Sincerely,

A handwritten signature in cursive script, appearing to read "Anne Muñoz-Furlong".

Anne Muñoz-Furlong
Founder



August 18, 2000

Mr. Joseph A. Levitt
Director
Center for Food Safety and Applied Nutrition
200 C Street, S.W.
Washington, DC 20204

Dear Joe:

Thank you once again for the opportunity to meet with you a few weeks ago. The Food Allergy Network (FAN) and the members of the American Academy of Allergy, Asthma and Immunology applaud the FDA's efforts in making the U.S. labeling regulations the best in the world. Our objective is to bring about improvements to these regulations that will improve the quality of life for the 6 to 7 million Americans who are affected by food allergies.

As I mentioned during our meeting, we would like to see food allergy labeling added to the FDA's "A list" of priorities with action items for this next year. To that end, per your suggestion, I would like to submit FAN's suggestions for food labeling improvements in priority order.

1. **Problem: Ingredient statements are written for scientists, not consumers.**

Food-allergic consumers must read every ingredient label every time they shop to determine whether or not a particular food is safe for them to eat. However, they often don't understand what they are reading. For example, milk is described in more than 15 different terms on a label, including casein, whey, curds, magnesium caseinate, and rennet casein, to name a few. Eggs can be listed a number of ways, including albumin or ovalbumin. Wheat can be listed a number of ways included as flour, semolina, durum, or farina. Other common allergy causing foods have similarly confusing synonyms.

When a doctor makes a diagnosis of food allergy, the doctor usually says to simply avoid milk, or eggs, etc. The learning curve for the parent or patient is steep when they begin to read ingredient labels and find that few products actually use common names such as milk or eggs. For the patient with multiple food allergies, it can be overwhelming and very frustrating to try to learn all the "surprise" ingredient terms for common foods.

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Solution: Use simple English terms. If the product contains milk, or eggs, or wheat, it should use these terms on the label. Ingredient statements should be simple enough for a 7-year-old to read and understand. Adults outside the patient's family, such as scout leaders, teachers, and childcare providers, read labels on behalf of food-allergic children. These individuals are not as well informed about the variety of synonyms found on food labels for common allergy causing foods, therefore, labels should be clear and easy for everyone to understand.

2. **Problem: "Non-dairy" is misleading, as it can include dairy.** Products labeled as "non-dairy" often contain casein, a milk derivative. Each year, FAN receives calls from parents whose milk-allergic children have suffered an allergic reaction because the parent believed the non-dairy flag on the product indicated that the product was dairy-free.

Solution: Avoid confusing terms such as non-dairy. If the product contains milk or milk byproducts, it should be listed as milk and the product should not be allowed to be advertised as "non-dairy".

3. **Problem: Major allergens are often "hidden" in terms such as Natural or Artificial Flavors.** Although present at low levels, there have been a number of allergic reactions in children from major allergens, such as milk, present in Natural Flavors. Further, when a parent or patient sees terms such as Natural or Artificial Flavors, they must call the manufacturer to determine whether the product contains one of the major allergens before they purchase that product. While some manufacturers willingly provide that information, too many tell the consumer not to buy any of their products or simply refuse to provide any assistance. If the individual is unsure whether the flavoring contains the allergen, they must avoid eating that food.

Solution: Clearly label all major allergens when present at potentially hazardous levels. A simple approach for flavors would be Natural *ALLERGEN NAME* Flavoring or Natural Flavors (Contains *ALLERGEN*), or a Contains *ALLERGEN* statement at the beginning or end of the ingredient declaration.

4. **Problem:** The use of precautionary allergen labeling is growing, further limiting the food choices of food-allergic consumers. While some companies are doing a very good job of carefully assessing the use of these statements, we are concerned that other companies are not as careful. The misuse of these terms is undermining the integrity of food labels. Some food-allergic consumers are ignoring

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the warning statements, seeing them simply as a company's approach to covering their legal liability. An example of an extreme use of precautionary allergen labeling is enclosed.

Solution: Develop a mechanism for enforcement of the guidelines set out in the 1996 FDA letter to the industry addressing the use of precautionary labeling.

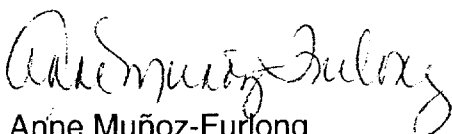
We have discussed these four food labeling improvements with industry groups, including the Grocery Manufacturers of America, the National Food Processors Association, and the Allergy Issues Alliance, which consists of major food-related trade associations. They are developing letters of support which should reach you soon.

In summary, food allergy is increasing as a major health concern. There is no cure. Food-allergic consumers must read all labels for all foods each time they shop — a tedious process that can take several hours.

Improvements in ingredient labels will enable patients to manage their food allergy more effectively and improve their quality of life. In addition to the medical risks associated with an allergic reaction, the problems and potential solutions we've identified will make life easier for the 6 to 7 million Americans affected by food allergies and for their family, friends, and other caregivers.

Please let me know if I can provide further information about food allergies from the consumer's perspective. Thank you for your time and attention to this matter.

Sincerely,



Anne Muñoz-Furlong
Founder

cc: Ken Falci, Ph.D., FDA
Christine Lewis, Ph.D., FDA
Robert Wood, M.D., AAAAI and FAN Medical Advisor
Steve Taylor, Ph.D., AAAAI and FAN Medical Advisor
Terence Furlong, FAN Chief Operating Officer